Veterans Health Administration response to the inadequate prostate implants performed at the Philadelphia VA Medical Center

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Introduction

- Initial Medical Event (ME) discovery was by the Philadelphia VAMC (PVAMC) staff.
- National Health Physics Program (NHPP) verified the ME and initiated complete review of all VHA programs.
- Programs at PVAMC and the Jackson VAMC were found to have inadequate procedures.

Introduction

- These programs were immediately suspended and the Veterans' follow-up care verified.
- Root causes of the performance errors were identified.
- Corrective actions have been taken.

VHA Initial Actions

- Coordinated with Nuclear Regulatory Commission (NRC), Region III, for corrective actions
- 7-point process identified within a Confirmatory Action Letter (CAL)
- Conducted a 100% evaluation of the PVAMC program [NHPP cited PVAMC for escalated enforcement.]
- Performed serial 10-case reviews of the 14 other existent or former VHA prostate brachytherapy programs

VHA Initial Actions

- VHA's Veterans Integrated Service Network (VISN) 4 convened an administrative board to conduct a root cause analysis at Philadelphia.
- VHA Associate Deputy Under Secretary convened the Clinical Risk Assessment Advisory Board (CRAAB) for prostate brachytherapy.
- A specific administrative board reviewed connectivity between treatment platforms and diagnostic imaging within the VHA.

Actions related to the CAL

- Conduct reactive inspections at brachytherapy programs. ***Completed in January 2009.***
- Develop and implement standard procedures for all VHA facilities that are authorized to perform these treatments. ***These procedures were issued in January 2009 and the facilities confirmed implementation in May 2009. Each has been re-inspected.***
- Correct the incompatible data transmission. ***VHA verified the data transmission problems were corrected prior to the CAL.***

Actions related to the CAL

- Identify the root causes and corrective actions to prevent recurrence of these medical events***.***

  Multiple reviews concluded the lack of appropriate quality assessment (QA) led to the failure to recognize and correct faulty implants.

  QA, incorporated into the VHA standard procedures, is verified annually during on-site inspections.

Actions related to the CAL

- Immediately suspend programs where medical events are identified for 20% of cases. Develop enhanced criteria.

  The National Radiation Safety Committee approved "suspend criteria" on November 13, 2008.

  The programs suspended by VHA had ceased prostate brachytherapy before the formal criteria were approved.

Actions related to the CAL

- Confirm, prior to restart, the implementation of all corrective actions and notify the NRC***.***

  This process was completed for the recently restarted program at VA Medical Center Cincinnati. Restarts are not anticipated for the remaining three suspended programs.

- Confirm that any new program within the VHA has fully implemented the VHA standard procedures and that individuals have received the training indicated within the CAL.

  To date, no new programs have been initiated.

Recent Actions

- Appointment of a new National Director for Radiation Oncology
- Identification of the flawed ME reporting process at PVAMC
- USH convened panel to examine ME criteria used by the VHA
- All prostate implants at PVAMC and Jackson VAMC are reviewed under criteria offered by the panel and approved by the Under Secretary for Health (USH)

Recent Actions

- VHA contacted NRC Region III to retract inappropriately reported ME
- OIG reported after separate investigation:
  - Quality assessment at the PVAMC and the Jackson VAMC were seriously deficient.
  - Absorbed dose metric, D90-values, were unrelated to outcome
  - ME reports were unrelated to toxicity
  - VHA and NRC should meet to agree on appropriate ME criteria

On-going Actions

- Develop the first data ever presented to address NRC reporting requirement 10 CFR 35.3045(c).

  Develop with the ITC/ATC and RTOG, database and technical report to provide expected doses to other organs and tissues associated with prostate volume implant brachytherapy.

- Conclude the external review of all prostate brachytherapy procedures at the Jackson VAMC.

  The review is being completed by a national quality assurance center for radiation oncology.

- Develop and implement a training module for the new ME criteria. ***A training module has been created.***

On-going Actions

- Develop credentialing guidelines for prostate brachytherapy to be used by VHA.
- Support and work with similar efforts underway in the relevant professional organizations.
- Coordinate with the National Cancer Institute Program Manager, for periodic on-site reviews by the RPC of medical physics operations within the VHA.
- Require that, in addition to following the VHA Standard Procedures, each program providing these procedures have a minimum of 10 cases annually reviewed externally.

Summary

- Prostate brachytherapy procedures within the VHA are of the most rigorous in our industry.
- Problematic initial evaluation of the PVAMC program and sensationalization by the press may have produced an unintended chilling effect on prostate brachytherapy procedures nationwide.

Summary

- A recent inter-agency review of the state of radiation oncology in the United States noted that a recent reduction in these procedures likely reflected the confused circumstances at Philadelphia.
- It is incumbent of those of us who guide these clinical and regulatory processes to get the answers right. Truth, not time, is of the essence when inappropriate assessment may eliminate a very useful and safe therapy.